510(K) Summary of Safety and Effectiveness

Submitter:

MAR 21 2003

VSM MedTech Ltd.
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Company Contact:

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Director of Regulatory Affairs and Clinical Research
Phone: (604) 738-8763
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Regulatory Identification:

Device Names: (1) BpTRU Vital Signs Monitor

(2) BpTRU Portable Automated Non-Invasive Blood Pressure and Temperature Monitor

Model Name: BPM-300

Device Classification Name: System, measurement, blood-pressure, non-invasive
Thermometer, electronic, clinical

Device Class: II

Regulation Numbers: CFR 870.1130 / 880.2910

Panel: Circulatory System Device Panel (74) / General Hospital (80)

Product Code: DXN / FLL

Classification Advisory Committee: Cardiovascular / General Hospital

Establishment Registration Number (Owner/Operator): 9034609

Predicate Device Information:

VSM Technology BpTRU Automated Non-Invasive Blood Pressure Monitor (Model BPM-100) as cleared by K994423, K002046 and K012636

Tycos Instruments Clinical Vital Signs Monitor, Model #52STP-E as cleared by K951193.

Device Description:

The BPM-300 is an automated, non-invasive blood pressure and temperature monitor that measures the blood pressure and pulse rate of patients using an upper arm cuff and the oral, axillary and rectal temperature using thermometry probes. The device uses standard blood pressure cuffs normally used in auscultation to measure the blood pressure in the upper arm. The device also uses stainless steel temperature probes, which are similar to design to commercially available probes from YSI, to measure the temperature from the oral, axillary and rectal regions.

The BPM-300 has two blood pressure operational modes: Manual and Automatic, which are used with the oscillometric technique to calculate systolic and diastolic blood pressure. Manual Mode is designed to take a single blood pressure measurement. Automatic Mode takes six measurements, discards the first, and displays the average of the last five readings. The cycle time, or minutes between measurements (from the start of one measurement to the start of the next measurement), can be selected in Automatic Mode. Readings can be reviewed in both Manual and Automatic Modes.

The BPM-300 includes two temperature measurement modes: Predictive and Continuous. Continuous Mode is designed to be used for taking extended length, monitoring measurements from the oral, axillary or rectal regions of the body. Predictive Mode is designed to calculate a single, quick (15 second) and accurate temperature measurement from either the oral or axillary region. There are two different color-coded temperature probes available for the BPM-300: oral/axillary (blue probe) and rectal (red probe). These temperature probes, which are manufactured for VSM by Yellow Springs Inc., also include the additional safety of a disposable probe cover, manufactured for VSM by Banta Healthcare.

The BPM-300 incorporates a battery, which allows for portable operation, a pole-mounting feature and computer/interface connectivity feature, through a USB port.

Indications for Use:

The BpTRU Vital Signs Monitor (Model BPM-300):

- Measures systolic and diastolic blood pressure and pulse rate in subjects 3 years of age or older.
- Measure temperatures in subjects 3 years of age or older.
- Is intended for use in physicians' offices, nursing units, and patient care areas of hospitals.

Intended Use:

The BpTRU is intended to:

- measure systolic and diastolic blood pressure and pulse rate in subjects
- measure systolic blood pressure in the range of 60 to 250 mmHg.
- measure diastolic blood pressure in the range of 40 to 160 mmHg.
- measure pulse rate in the range of 40 to 200 beats per minute.
- measure temperature in the range of 28°C to 43°C (82.4°F to 109.4°F) for Continuous (Monitoring) Measurements and 35°C to 39°C (95.0 to 102.2°F) for Predictive (Single) Measurements.
- be operated by physicians, nurses, or other qualified medical personnel.
- be used in physicians' offices, nursing units, and patient care areas of hospitals.
- be pole-mounted, wall-mounted or used on a table top.
- be battery or mains operated.
- be connected to a PC via a USB port for data interchange.

Technological Characteristics:

The blood pressure functionality of the BPM-300 has the equivalent technological characteristics as the predicate device [BpTRU Automated Non-Invasive Blood Pressure Monitor (Model BPM-100)].

The sensor used with the temperature probe is a negative temperature coefficient thermistor. The sensor is mounted within a stainless steel probe.

The temperature probes have a stainless steel shaft with a santoprene handle and a polyurethane-coated coiled cable. They are manufactured for VSM by YSI Incorporated. (Refer to **Appendix B.**)

The temperature probe covers are manufactured from ethylene methyl acrylate copolymer film. They are manufactured for VSM by Banta Healthcare. (Refer to **Appendix C.**)

Testing:

The blood pressure feature of the BPM-300 was tested and meets the requirements of AAMI/ANSI SP10: 1992 (Electronic or automated sphygmomanometers).

The continuous temperature feature of the BPM-300 was tested and meets the requirements of ASTM E1112-00 (Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature).

The predictive temperature feature of the BPM-300 was tested in a clinical validation study and the results demonstrate that the predictive measurements are accurate as compared to the continuous temperature.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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VSM MedTech Ltd.
c/o Mr. Daryl Wisdahl
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15th floor, 675 West Hastings
Vancouver, BC V6B 1N2
Canada

Re: K023078
Trade Name: BpTRU™Vital Signs Monitor, Model BPM-300
Regulation Number: 21 CFR 870.1130 and 21 CFR 880.2910
Regulation Name: Noninvasive Blood Pressure Measurement System and Clinical Electronic Thermometer
Regulatory Class: Class II (two)
Product Code: DXN and FLL
Dated: December 20, 2002
Received: December 23, 2002

Dear Mr. Wisdahl:

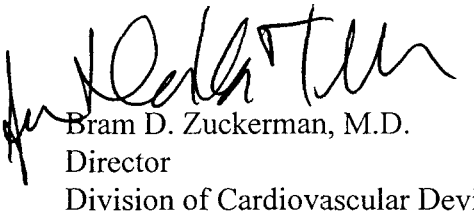
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: **K023078**

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter USE**

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K023078